REMARKS

Claims 53-54, 56, 59, 62-70, 77-78, 80-91, and 112-117 are pending. Claims 55, 57-58, 60-61, 79 and 92-111 have been canceled without prejudice and without acquiescence. Claims 53, 54, 56, 59, 62, 63, 77, and 78 have been amended without prejudice and without acquiescence. Claims 112-117 have been added and support can be found throughout the entire specification and the previously pending claims. Applicants retain the right to file a continuation and/or a divisional application to any canceled claims. No new matter has been added.

The issues outstanding in this application are as follows:

- Claims 53, 62-70, 77-79 and 82-91 were objected to as encompassing non-elected subject matter.

- Claims 53, 54, 56, 58, 59 and 62-70 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5 and 9 of U.S. Patent No. 5,972,609.

- Claims 53, 62-70, 77-79, 82-88 and 90 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tinsley et al.

- Claims 54, 56, 58, 59, 80 and 81 were rejected under 35 U.S.C. § 103(a) as being unpatentable overTinsley et al.

- Claims 59, 62-70, 78 and 82-91 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification.

- Claims 53, 62-70 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

- Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Claim Objection

Claims 53, 62-70, 77-79 and 82-91 were objected to as encompassing non-elected subject matter.

Applicants assert that the pending claims relate to the elected subject matter.

II. Rejection under Double Patenting

Claims 53, 54, 56, 58, 59 and 62-70 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5 and 9 of U.S. Patent No. 5,972,609. Applicants traverse.

Applicants submit that the present claims are not obvious over the disclosure of US-A-5972609. US-A-5972609 is concerned with the A promoter of utrophin. There is no disclosure in that document of any second promoter between exon 2A and 3 of utrophin as is claimed in the present invention. The present invention results in the identification of a second promoter present in the intron between exons 2A and 3, and identification of a new exon 1B. This is labelled B-utrophin in Figure 5C. Thus, the disclosure of WO96/34101 and US-A-5972609 relate to utrophin promoter A and the first utrophin gene exon which is represented as exon 1A in Figure 5C of the present application. The plasmids YAC 23 exemplified in WO96/34101 that are used to identify the utrophin promoter are described in WO96/34101 as only containing human utrophin exons 1 and 2 (see page 20, lines 14 to 23).

In contrast, the present application focuses on the intron between exons 2A and 3 and in particular the identification of a second promoter, the B promoter within this region and a new exon 1B. Thus, the presently claimed subject matter is directed to the novel promoter sequences identified in accordance with the present invention when not associated with utrophin coding sequences, and the use of these promoter sequences to drive expression of heterologous sequences. The invention also relates to new exon 1B, not previously identified in the prior art.

The B promoter sequences and exon 1B are not described in WO96/34101 nor in US-A-5972609, and indeed are found in a region of the utrophin gene that was not analysed in WO96/34101 for identification of promoter sequences.

While the Examiner has indicated that the claims of both the '609 patent and the claims of the present application are drawn to constructs encompassing the human utrophin promoter region, as is explained above and demonstrated in Figure 5C of the present application, different utrophin promoters are involved. The '609 patent is directed to the A promoter of utrophin. In contrast, the present application is directed to the previously unidentified B promoter of utrophin.

The '609 patent does not suggest that an additional promoter might be present within the utrophin gene. Furthermore, the '609 patent does not teach or suggest that such a second promoter leads to expression of a protein which has a different signal sequence and N terminus to that described in the '609 patent. The utrophin mRNA described in the '609 patent commences with exons 1A and exons 2A. By contrast, mRNA transcribed from the B promoter described in the present application, commences with exon 1B. Exon 1A and exon 2A are not present.

Given that the inventors of the '609 patent do not describe or suggest that a second utrophin promoter might be present in the utrophin gene, we submit that it was not obvious that such a second promoter existed and thus the present claims are patentably distinct from the '609 patent.

III. Rejection under U.S.C. 102

Claims 53, 62-70, 77-79, 82-88 and 90 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tinsley et al. Applicants traverse.

The Examiner has referred to Tinsley et al as teaching generally a clone of the promoter region of human utrophin. While this is true, it should be recognized that the promoter described in Tinsley is the A promoter. As is demonstrated in Figure 5C of the present application, this is quite distinct from the B promoter which has been described in the present application

The claims of the present application are directed firstly to the B promoter in the absence of utrophin coding sequences. Thus, a prior art clone of human utrophin would not fall within the scope of these claims since these claims are only directed to the isolated

promoter in the absence of such utrophin coding sequences. Claims are also presented directed to the utrophin B promoter operably linked to heterologous sequences.

While the Examiner suggests that Tinsley et al teaches the general location of the promoter, its function and its minimally necessary component, applicants note again that these sequences in Tinsley et al are those of the A promoter and not those of the B promoter which is now claimed. Given that Tinsley et al only conducted a detailed analysis of a clone containing human utrophin exons 1 and 2 to identify their promoter sequence, it is quite apparent, by review of Figure 5C of the present application that this would not lead to identification of the B promoter which lies downstream of exon 2A, in the intron between exons 2A and 3.

Furthermore, Applicants have amended independent claims 53 and 62 without prejudice and without acquiescence to incorporate the subject matter of claim 58, which is not anticipated by Tinsley. Current claim 63 depends from claim 59, which is also not anticipated by Tinsley. Thus, Applicants assert that the presently pending claims are not anticipated by Tinsley et al.

IV. Rejection Under 35 U.S.C. 103

Claims 54, 56, 58, 59, 80 and 81 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tinsley et al. Applicants traverse.

As indicated above, the claims of the present application are directed firstly to the B promoter in the absence of utrophin coding sequences. Thus, a prior art clone of human utrophin would not fall within the scope of these claims since these claims are only directed to the isolated promoter in the absence of such utrophin coding sequences.

While the Examiner suggests that Tinsley et al teaches the general location of the promoter, its function and its minimally necessary component, we note again that these sequences in Tinsley et al are those of the A promoter and not those of the B promoter which is now claimed. Given that Tinsley et al only conducted a detailed analysis of a clone containing human utrophin exons 1 and 2 to identify their promoter sequence, it is quite apparent, by review of Figure 5C of the present application that this would not lead to

identification of the B promoter which lies downstream of exon 2A, in the intron between exons 2A and 3. Thus, Applicants assert that the presently pending claims are non-obvious over Tinsley et al.

V. Rejections Under 35 U.S.C. 112

A. First Paragraph

Claims 59, 62-70, 78 and 82-91 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification. Applicants traverse.

Applicants respectfully traverse as the current claims are fully supported by a written description in the specification demonstrating possession of the claimed invention. In this regard it is initially noted that the current independent claims 59 and 78 relate to an isolated nucleic acid sequence having at least 90% identity with the nucleotides shown 5' to position 1440 in figure 1 or having at least 90% identity with the nucleotides numbered 1199-1440 in figure 1 or a nucleotide sequence encoding a polypeptide with an amino acid sequence having at least 95% identity with the polypeptide sequence in figure 1. This subject matter is fully described in the specification in compliance with §112 based on the description of SEQ ID NOs:1 and/or Figure 1 and further descriptions in the specification, as it is well settled that an Applicant need not limit the claims to that subject matter having *ipsis verbis* description. In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)). Further, written description must be reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993).

In regard to the foregoing, Figure 3 illustrates the considerable sequence overlap among the identified utrophin promoters. This information provides more than an adequate structural description of the entire scope of the claimed invention and demonstrates possession of the invention in compliance with the written description requirement. As explained in the specification, it was routine in the art as of the filing date to make determine

similarity or homology of nucleic acid sequences by using standard techniques defined on pages 8 and 9 of the specification.

In view of the foregoing and currently claimed subject matter, Applicants submit that the rejection is now moot and respectfully request that it be withdrawn.

A. Second Paragraph

Claims 53, 62-70 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants traverse.

In order to advance the prosecution of the present application, the term "substantially" has also been deleted in claim 53, and claims 62-70 depend from claim 59. Thus, Applicants respectfully request that the rejection be withdrawn.

In view of the above, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02428US0 from which the undersigned is authorized to draw.

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Respectfully submitted,

By _____
Melissa W. Acosta, Ph.D.
Registration No.: 45,872
FULBRIGHT & JAWORSKI L.L.P.
2200 Ross Avenue, Suite 2800
Dallas, Texas 75201
(214) 855-7163
(214-855-8200 (Fax)
Attorney for Applicant